I. AMENDMENTS

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 milligrams, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 2. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions and

a dry coating only on one or more of said microprotrusions; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 3. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusion being adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 4. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent; said coating having a thickness equal to or less than the thickness of the microprotrusions;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 5. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 6. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having been formed by etching said plurality of microprotrusions from a thin sheet and folding the microprotrusions out of a plane of the sheet; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 7. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises; and

wherein the pharmacologically active agent is selected from the group consisting of ACTH (1-24), calcitonin, desmopressin, LHRH, goserelin, leuprolide, buserelin, triptorelin, other LHRH analogs, PTH, vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, FSH, EPO, GM-CSF, G-CSF, IL-10, glucagon, GRF, analogs thereof and pharmaceutically acceptable salts thereof.

Claim 8. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of the pharmacologically active agent desmopressin;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 9. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent, said coating having been applied by dip coating;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 10. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent, said coating having been applied by spray coating;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 11. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent, said coating having been applied by spray coating; said spray comprising droplets having a volume of about 10 picoliters to about 200 picoliters;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 12. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry non-contiguous coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 13. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 0.25 milligrams, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 14. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 50 centipoises.

Claim 15. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent, said coating having a thickness over a surface of said member of less than about 50 micrometers;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 16. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent, said coating having a thickness over a surface of said member of less than about 25 micrometers;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 milligrams/milliliter and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 17. (Withdrawn) A device for transdermally delivering a pharmacologically active agent, the device comprising:

a member having a plurality of stratum corneum-piercing microprotrusions; and

a dry coating on said member; said coating, before drying, comprising an aqueous solution of an amount of a pharmacologically active agent and an adjuvant;

wherein said pharmacologically active agent is sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg, said agent having aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 18. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 19. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto only one or more of said microprotrusions; and

drying said applied aqueous solution to form a dry agent-containing coating only on one or more of said microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 20. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; said microprotrusions adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 21. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions.

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 22. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 23. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; said pharmacologically active agent selected from the group consisting of ACTH (1-24), calcitonin, desmopressin, LHRH, goserelin, leuprolide, buserelin, triptorelin, other LHRH analogs, PTH, vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, FSH, EPO, GM-CSF, G-CSF, IL-10, glucagon, GRF, analogs thereof and pharmaceutically acceptable salts thereof; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 24. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent desmopressin onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claims 25-27. (Canceled)

Claim 28. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member in a non-contiguous pattern; and

drying said applied aqueous solution to form a dry agent-containing non-contiguous coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 29. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 0.25 milligrams and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 30. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 50 centipoises.

Claim 31. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 50 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 32. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 25 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 33. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

providing an aqueous solution comprising said pharmacologically active agent and an adjuvant;

applying said aqueous solution onto the member; and

drying said applied aqueous solution to form a dry agent-containing and adjuvant-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 34. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 1 mg/cm^2 of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claim 35. (Original) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 0.5 mg/cm^2 of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility of greater than about 50 mg/ml and said aqueous solution having a viscosity less than about 500 centipoises.

Claims 36-37. (Canceled)

Claim 38. (Previously presented) A method of transdermally delivering a pharmacologically active agent to a patient, comprising the steps of:

providing a microprotrusion member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusion member having a coating disposed thereon, said coating including at least one pharmacologically active agent, said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg; and

applying said microprotrusion member to a skin site on the patient, whereby said plurality of stratum corneum-piercing microprotrusions pierce the stratum corneum and deliver said pharmacologically active agent to the patient,

wherein said delivered pharmacologically active agent has improved pharmacokinetics compared to pharmacokinetics after subcutaneous injection.

Claim 39. (Previously presented) The method of Claim 46, wherein said pharmacologically active agent is selected from the group consisting of ACTH(1-24), calcitonin, desmopressin, LHRH, LHRH analogs, goserelin, leuprolide, PTH, vasopressin, deamino[Val4, D-Arg8) arginine vasopressin, buserelin, triptorelin, interferon alpha, interferon beta, interferon gamma, FSH, EPO, GM-CSF, G-CSF, IL-10, glucagon, growth hormone releasing factor (GRF), and analogs and pharmaceutically acceptable salts thereof.

Claim 40. (Previously presented) The method of Claim 38, wherein said improved pharmacokinetics comprises increased bioavailability of said pharmacologically active agent.

Claim 41. (Previously presented) The method of Claim 38, wherein said improved pharmacokinetics comprises an increase in C_{max}.

Claim 42. (Previously presented) The method of Claim 38, wherein said improved pharmacokinetics comprises a decrease in T_{max}.

Claim 43. (Previously presented) The method of Claim 38, wherein said improved pharmacokinetics comprises an enhanced absorption rate of said pharmacologically active agent.

Claim 44. (Previously presented) The method of Claim 38, wherein said coating is formed from an aqueous solution having solubility greater than approximately50 mg/ml.

Claim 45. (Previously presented) The method of Claim 44, wherein said aqueous solution has a viscosity less than approximately 500 centipoises.

Claim 46. (Previously presented) The method of Claim 38, wherein each of said plurality of stratum corneum-piercing microprotrusions has a length less than approximately 500 microns.